Written Statement of

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to the

SUBCOMMITTEE ON HEALTH AND ENVIRONMENT

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

Committee on Commerce

United States House of Representatives

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Summary of Key Points

CASAC Comments on EPA Draft PM Research Needs Documents

1. Focus research needs and strategy on most critical risk assessment uncertainties
2. Develop strategy with awareness that sole causality of PM is not confirmed
3. Give strong emphasis to long-term health effects
4. Give strong emphasis to personal exposures of presumed susceptible subpopulations
5. Give strong emphasis to potential mechanisms of health effects
6. Consider examining health benefits from past reductions of PM
7. Emphasize cross-disciplinary, interagency, and international research interactions
8. Emphasize need for expanding research funding to fill critical information gaps

Personal Views Regarding the O_3 and PM Standards

1. Concur with proposed O_3 standard
2. Concur with proposed PM_{10} standard
3. Support establishment of fine PM standard
    a. Prefer standard based on $PM_{1.0}$ rather than $PM_{2.5}$
    b. There is considerable uncertainty about fine PM and health
    c. Prefer 50 $\mu g/m^3$ 24 hr and 20 $\mu g/m^3$ annual standards
4. Other issues:
    a. It is important to increase PM research support
    b. The research needs to be coordinated and sustained
    c. Air pollution needs to be considered in a more integrated manner

Introduction

I have served on the Clean Air Scientific Advisory Committee (CASAC) of the Environmental Protection Agency (EPA) since 1992, and was recently appointed Chairman of that Committee. I am Director of External Affairs of the Lovelace Respiratory Research Institute in Albuquerque, New Mexico, a private, nonprofit organization which conducts respiratory health research sponsored by government, industry, and philanthropy, and President of its nonprofit operating subsidiary, the Lovelace Biomedical and Environmental Research Institute. My career has been devoted to the detection, characterization, and reduction of risks to human respiratory health caused by inhalation of toxic materials. My academic training is in veterinary medicine, and my expertise is understanding similarities and differences between the function of animal and human respiratory systems and their responses to inhaled materials to improve our use of laboratory data to predict human health risks. My research has focused primarily on inhaled particles, but I have also studied the effects of ozone, nitrogen dioxide, and other pollutants.

I am pleased to respond to your request to comment on the activities and perspectives of CASAC in reviewing the ozone (O_3) and particulate matter (PM) criteria documents and staff papers, and on my views of the scientific information on those pollutants and future research needs. These comments represent my personal views, and only represent positions of CASAC when I describe the summary positions CASAC has submitted in writing to the EPA Administrator. My personal opinions, however, are consistent with the summary positions submitted by CASAC on the scientific knowledge, proposed standards, and research needs concerning both O_3 and PM.

CASAC Review of the O_3 and PM Criteria Documents and Staff Papers

The establishment and functions of CASAC, the history of the National Ambient Air Quality Standards (NAAQS) for O_3 and PM, the activities and positions of CASAC in reviewing the most recent Criteria Documents and Staff Papers for these pollutants, and the key scientific information considered in regard to the standards currently proposed by EPA were recently summarized by Dr. George Wolff, immediate past Chairman of CASAC, in his written statement to the House Committee on Science, Subcommittee on Energy and Environment on March 12, 1997[1]. I have reviewed Dr. Wolff's statement and consider it an accurate description of the above facts, events, and issues. Rather than reiterating this material, therefore, I refer the Subcommittees to Dr. Wolff's March 12, 1997 statement.

CASAC Comments on PM Research Needs

Following its review of the PM Criteria Document and Staff Paper, CASAC and the same consultant panel which reviewed these documents reviewed two additional documents drafted by EPA, *Particulate Matter Research Needs for Human Health Risk Assessment*[2], and *Particulate Matter Research Program Strategy*[3]. On March 12, 1997, CASAC submitted its summary comments on these documents to the EPA Administrator[4]. In its comments, CASAC acknowledged, as it had previously, that significant uncertainties remained regarding the health risks of ambient PM, and strongly encouraged EPA to expanded its PM research program and focus on reducing key uncertainties in anticipation of future reviews of the PM NAAQS. The

following key issues (not prioritized) were noted among CASAC's suggestions for improving the documents:

1. Focus research needs and strategy on most critical risk assessment uncertainties
2. Develop strategy with awareness that sole causality of PM is not confirmed
3. Give strong emphasis to long-term health effects
4. Give strong emphasis to personal exposures of presumed susceptible subpopulations
5. Give strong emphasis to potential mechanisms of health effects
6. Consider examining health benefits from past reductions of PM
7. Emphasize cross-disciplinary, interagency, and international research interactions
8. Emphasize need for expanding research funding to fill critical information gaps

My Personal Views Regarding the O_3 and PM Standards

Ozone

On a scientific basis, I support EPA's proposal to replace the current one-hour O_3 standard of 0.12 ppm with an eight-hour standard at a slightly lower concentration. The proposed change is founded on information indicating that multiple-hour exposures below 0.12 ppm can affect lung function and symptoms in children and adults exercising outdoors. This change addresses two goals that have scientific validity. First, the new standard reflects an advancement in our understanding of the health impacts of O_3, in that it recognizes that multiple-hour exposures can cause adverse effects at concentrations lower than concentrations causing similar effects during one-hour exposures. Second, the new standard is predicted to result in improved protection by reducing the health impact of O_3 below that occurring under the present standard. The proposed

level of 0.08 ppm is estimated to represent a reduction in exposure concentration below those which are thought to occur over eight-hour periods under the present one-hour standard.

On a practical basis, however, I would call the Committee's attention to two important issues. First, as our ability to detect subtle responses of lung tissue to O_3 improves, and as we gain more refined information from especially susceptible humans exposed in the environment and in laboratories, it is becoming increasingly apparent that there will probably be no clear threshold for detecting responses at exposure concentrations within the concentration range amenable to regulatory control. It should be understood that our growing ability to detect and study responses to exposures to O_3 and other pollutants down to, and perhaps including, background (uncontrollable) concentrations is necessarily accompanied by an increasing demand on our judgment of: 1) when cellular responses should be considered sufficiently adverse to warrant regulatory action; and 2) our responsibility for ensuring that the most sensitive citizen is protected from transient effects under all potential combinations of location and activity.

A second practical point should be weighed in considering the most appropriate approach to mitigating the health impacts of O_3. Let me preface this point by making it clear that my expertise does not lie in the area of cost-benefit analysis. In considering changing the standard to increase health protection, it should be remembered that the current standard is not being met in many areas, nor is it obvious that the current standard would be met in some of these areas if it was retained for another five years. It is certainly not clear that the proposed standard will be more readily met than the existing standard. According to information I obtained last month via the Internet, EPA's Office of Air Quality Planning and Standards reported that, in December 1996,

approximately 101 million Americans lived in areas violating the current O_3 standard. That is a substantial portion of our population. While I support the proposed change as logical from a scientific viewpoint, I would point out that it should also be considered that an equal or greater overall health benefit might be derived by using the nation's resources to achieve compliance with the present standard in presently noncompliant regions, than by enforcing nationwide compliance with a more restrictive standard.

Particulate Matter

PM_{10} Standard

I am on record as a member of CASAC as supporting continuation of the present annual and 24-hour PM_{10} standards at their present concentrations, adopting perhaps, a more robust form to increase the stability of compliance status. That is still my opinion today. I do not believe it is wise to ignore the potential health impacts of the coarser portion of the respirable ambient PM. On the other hand, I do not recommend lowering the concentration of the PM_{10} standard, especially in view of the likelihood that a fine particle standard will be implemented.

Fine Particle Standard ($PM_{2.5}$)

I support EPA's proposal to implement an additional PM standard targeting the smaller portion of respirable airborne PM. This change recognizes the reality, which health and atmospheric scientists have communicated for many years, that airborne PM is not a homogenous class of material, but is a collection of diverse materials common only in their existence in the air as particles. The frailty of the logic of a single PM standard is illustrated by considering the parallel unreasonableness of having only a single "gas" standard comprised of a concentration limit for all

pollutant gases combined. Implementing a fine particle standard is a positive step toward dealing with airborne PM as a collection of subpopulations of particle types having different sources, differing (although probably overlapping) health consequences, and requiring different control strategies. Although selecting a fine particle standard is problematic, continuing indefinitely to treat all PM as a single class is not scientifically reasonable.

It would be ideal to precede a decision regarding a fine PM standard with the collection of better data on fine PM. The decision to promulgate and implement a fine PM standard could be approached with much greater confidence if we had better knowledge of the present concentrations and composition of fine PM across the country. As a scientist, I consider it an unfortunate reality that the only way we are likely to acquire this knowledge is by promulgating a regulation requiring the measurements.

Size is a more reasonable characteristic than chemical composition for beginning to distinguish between the two principal classes of PM. Not all, but the large majority of the finer particle mass consists of particles generated from human activities, principally from combustion of biomass and fossil fuels. These particles are primarily formed by condensation of vapors in the atmosphere or during combustion. This size class contains the majority of airborne carbon, metals, organic compounds, sulfur compounds, and acids. Not all, but the large majority of the coarser respirable portion of ambient PM mass is generated by the fracturing or abrasion of larger materials and suspension in the air by the mechanical forces of human activity and wind. This size class is largely mineral in nature and much of it is derived from soil.

Based on present knowledge, it is reasonable to generalize that the finer fraction of airborne respirable PM is more toxic when inhaled than the coarser fraction. The present body of epidemiological information supporting this judgment is not large and its interpretation is under debate. Such as it is, however, it does appear to suggest that finer particles have greater health consequences per unit of mass than coarser particles. Information from laboratory studies points toward an increasing toxicity with decreasing particle size of the same material, and suggests that the known differences in composition should render the finer portion of respirable PM more toxic than the coarser portion. Moreover, it is presently more practical and less costly to begin implementing selective PM monitoring based on particle size, than on chemical composition.

I prefer a 1.0 micron criterion for fine PM mass to the proposed 2.5 micron criterion. The most appropriate particle size cut-off for distinguishing between the major classes of PM is arguable, because the particle size composition of PM varies by site and in time, and because the size ranges of the two classes always overlap to some extent. The proposed 2.5 micron cut-off size has a practical basis in the present availability of such monitors, their present use in some areas, and the small, but growing, body of information on air quality and health using this size cut-off. However, although the proposed 2.5 micron size criterion can be argued to provide a useful distinction between the two major size classes of PM mass in many situations, I prefer that the criterion for fine particle mass be set at 1.0 micron. This criterion would more clearly limit measurements of fine particles to the largely combustion-derived PM I believe to be of greatest toxicological concern by more completely excluding the smaller-sized tail of the coarser, largely soil-derived portion of PM. I am concerned that in New Mexico and other arid regions with

alkaline soils, the substantial portion of soil-derived PM that can exist as $PM_{2.5}$ may cause noncompliance with a standard aimed at controlling a different class of PM. Moreover, I believe that a 1.0 micron criterion would better distinguish between the deposition, clearance, and penetration behaviors of coarse mode and fine mode PM in the respiratory tract.

Level of the Fine Particle Standard

I believe that a fine particle standard should be implemented at a concentration and in a form that places some degree of increased pressure on peak ambient concentrations. I do not believe, however, that our present understanding of the relationship between PM and health provides a confident basis for implementing a standard that necessitates crippling expenditures or extreme changes in lifestyle or technology.

The epidemiological associations between PM and health should not be ignored. These associations are persistent across ranges of locations, climatic conditions, populations, and investigators. Present information indicates a logical coherence of effects across health measures, including mortality in elderly people with preexisting lung and heart disease, and morbidity reflected by the number and severity of asthmatic episodes, medication use, measured lung function, and visits to medical facilities for respiratory problems. While we do not presently understand the relationships between PM and health very well, it appears that the linkages suggested by epidemiology cannot be attributed solely to statistical artifact. In my view, it would be an abdication of responsibility to ignore this information, or to delay acting on it until the relationships between PM and health were fully understood in all detail.

On the other hand, the present uncertainties concerning the relationships between PM and health appear to warrant caution in the implementation of regulatory controls. For example:

1. We do not yet have a very solid foundation of information linking adverse health effects in humans directly to fine particles. Only a small portion of our present epidemiological information is derived from studies in which concentrations of fine PM were actually measured. Studies indicating relationships between particle size and health effects have not provided the ability to determine a specific size criterion representing the best benchmark for increased risk.

2. There is a great deal of uncertainty concerning the extent to which effects associated with PM in the epidemiological studies might have been confounded by effects of other pollutants. It is recognized that PM is always present together with other airborne pollutants, and that the observed effects thus always occur in association with exposures to a mixture. The extent to which PM was the sole causal agent, was the principal among multiple causal agents, or acted as a surrogate "dose" indicator for the effects of the mixture is not well known at this time.

3. The epidemiological information on mortality does not provide a very good understanding of the individuals most affected by PM, or their exposures. Epidemiology suggests that increases in mortality temporally associated with increases in PM are expressed with the greatest significance in older people with preexisting lung and heart disease, and it seems

logical that these people might be at greatest risk. However, these are statistical associations which do not tell us which individual deaths might have been hastened by PM. For this reason, we know little about the locations or activities of the decedents preceding their deaths. Exposure data are from outdoor area monitors; thus, we do not know the personal outdoor or indoor exposure of any individual that died during the study period. Because the area monitoring data are based on mass measurements, we have a poor understanding of the composition of PM breathed by the decedents.

4. We do not yet have a very good understanding of the biological plausibility of mortality from PM at the concentrations to which decedents were likely exposed. We can speculate about mechanisms, or processes, by which PM might cause death, but there is yet little evidence that these mechanisms function at the PM exposure concentrations indicated by epidemiology. Our information from laboratory studies and our knowledge of the consequences of occupational exposures to particles do not suggest that people should die when exposed to PM at the levels indicated by epidemiology. Laboratory scientists have only recently begun studies using animals with lung and heart conditions, and ages, modeling those of the populations thought to express PM-associated mortality. While we are making progress in understanding how inhaled particles may contribute to adverse effects, including mortality, but the biological linkages between PM and death at the exposure concentrations of concern will remain speculative during the time frame of the present PM NAAQS review.

Epidemiologists, laboratory scientists, and atmospheric scientists are now working to improve our understanding in all of the areas described above, and it can be assumed that our foundation of knowledge for designing appropriate regulatory controls will improve. At present, while we have sufficient knowledge to act, we have insufficient knowledge to warrant draconian measures.

I am on record, through my participation on CASAC, as recommending annual and 24-hour standards for $PM_{2.5}$ at mass concentrations of 20 and 50 micrograms per cubic meter, respectively, implemented in a robust form. My view has not changed. I agree with the 24-hour concentration standard, and with the forms of the 24-hour and annual standards, proposed by EPA. I believe that an annual concentration standard of 20 micrograms per cubic meter, while above the range proposed by EPA, would be sufficient to place increased pressure on fine particle concentrations in the most critical areas, and thus to increase health protection. Implementation of this standard should be accompanied by increased effort to gain better knowledge on which to base a decision regarding the need for a more stringent standard.

Because the present epidemiological data do not provide evidence of a threshold for the effects of PM, it is understandable that some individuals and groups propose adopting a concentration standard at or below the lower end of the range proposed by EPA. It is my view, however, that the current evidence for a linear, no-threshold response is more an outcome of the limitations of our present data and the mathematical approaches used to model present data than it is an accurate reflection of exposure-dose-response realities. I acknowledge the possibility that continued research may demonstrate that biological responses can be detected at PM levels down to background, just as is the case for O_3. At this time, however, I do not believe we are

sufficiently well informed to make the judgment that regulating fine PM to near background levels is an appropriate national commitment.

Associated Issues

Importance of Increased Research Support

The current level of national support for epidemiological, laboratory, and atmospheric research on air pollution is badly inadequate in comparison to the magnitude of the health and socioeconomic stakes. While the nation's investment in research on pollutants and their effects is not made solely through EPA, the levels of funding projected by EPA to be available to resolve the uncertainties described above is not adequate. For example, an effort on the order of $50 million/ year on PM research alone would be a much more reasonable investment at this time than the present projection of less than one-half of that amount.

Need for Sustained, Nationally Coordinated Research Effort

The present approach to implementing the Clean Air Act results in a cyclic emphasis on individual pollutants at approximately five-year intervals. Research momentum peaks and is then lost as the emphasis and funding incentives swing from pollutant to pollutant. Research programs should be implemented and sustained using a strategy aimed at improving decisionmaking at subsequent reviews, or to meet future needs, rather than providing incentives and funding opportunities on a "pollutant of the moment" basis.

Acquiring the information that will be needed to identify and manage environmental health risks from airborne pollutants in the future will require the efforts of many medical and scientific

disciplines, research institutions, and funding agencies. Moreover, best advantage could be gained by providing coordination of work funded by both the Federal and private sectors. As the issues and societal choices become increasingly complex, our information needs can be best met by coordinating efforts and information transfer across research disciplines in a continual, iterative manner which provides frequent feedback among epidemiologists, laboratory scientists, and regulatory bodies, and current, objective information to the public. There is presently no national center of coordination for this type of integrative effort. Such a center is needed.

Need for Considering Health Risks from Air Pollution in a More Integrated Manner

There is an urgent and growing need for the nation, perhaps through EPA and its Scientific Advisory Board committees, to develop strategies for identifying, characterizing, and managing health risks in a manner that better integrates risks from the total pollutant burden.

All human exposures to environmental air pollutants occur as exposures to mixtures, yet our approach to implementing the Clean Air Act is driven by consideration of individual pollutants or pollutant classes one at a time. As described above, it is difficult to determine the individual health impacts of single pollutants outside the laboratory. This difficulty is being compounded as pollution levels are decreasing, and can only be expected to worsen in the future. Moreover, because multiple pollutants can cause a given health effect (eg, lung inflammation), standards which protect the public from the effects of individual pollutants may not provide adequate protection from a combination of pollutants, each meeting the standard. Despite these realities, there is presently little emphasis on research or risk management activities aimed at dealing with the health burden of air pollution in an integrative manner.

References

1. Wolff, G.T., “The CASAC Review of the Ozone and PM Standards”, written statement to the House Subcommittee on Energy and Environment, Committee on Science, Washington, DC, March 12, 1997.
2. U.S. EPA Office of Research and Development, “Particulate Matter Needs for Human Health Risk Assessment”, External Review Draft NCEA-R-0973, October 25, 1996.
3. U.S. EPA Office of Research and Development, “Particulate Matter Research Program Strategy”, External Review Draft NHEERL MS-97-019, October, 1996.
4. Mauderly, J.L. and Wolff, G.T., “ Evaluation of Research Needs for the Particulate Matter National Ambient Air Quality Standards (NAAQS)”, Clean Air Scientific Advisory Committee (CASAC) comments on the October 1996 draft documents (references 1 and 2 above), EPA-SAB-CASAC-LTR-97-004, U.S. EPA, Washington, DC, March 12, 1997.